

File(s): FDA summary-outline

Attached is a draft of an FDA summary piece for use in the field that includes a discussion of FDA's regulatory authority and the tobacco specific proposals. Its written to be informative, rather than persuasive.

I have omitted reference to ADAMHA at this point but I think it could be helpful, any thoughts?

I'll share with MF and others here for review and comment as well. Thanks.

Note for Woodward, Ellis

From: Woodward, Ellis
Date: Wed, Aug 16, 1995 3:33 PM
Subject: Communications Mtg Thursday
To: Laufer, David

Can you make an FDA communications meeting tomorrow at 1:30 w/Gary Auxier and me? Per our discussion this morning, I think we need to work on both message (with the polling data) and start planning for some of the contingencies. Pls advise. Thanks.

Note for Woodward, Ellis

From: Woodward, Ellis
Date: Wed, Aug 16, 1995 12:51 PM
Subject: RE:
To: Walls, Tina

I was counting on it. The meeting will be a noon. I have a call into Dawson to determine where. Will keep you posted. Thanks.

From: Walls, Tina on Wed, Aug 16, 1995 10:32 AM
To: Woodward, Ellis
Cc: Firestone, Marc

if it is appropriate to have a state govt affairs type at the tuesday meeting, i am happy to attend. let me know. thanks

Note for Woodward, Ellis

From: Woodward, Ellis
Date: Wed, Aug 16, 1995 12:50 PM
Subject: FW: ADAMHA REgs
To: Laufer, David; Merlo, Ellen

We should discuss.

From: Nicoli, David on Wed, Aug 16, 1995 10:03 AM
Subject: ADAMHA REgs

To: Han, Vic; Laufer, David; Woodward, Ellis
Cc: Firestone, Marc; Parrish, Steve

Dan Jaffe from ANA reported to me that a reporter that was interviewing him said that he had spoken w/Shalala, who said the ADAMHA regs are coming out next week.

Besides an FYI, I think you will want to consider in advance what we say in response to their issuance. One could argue that we could leverage off their issuance along the lines of the FDA Insider Report—ie, that Congress made a policy decision 3 years ago to give states the responsibility in this area, that was the right decision, that HHS has sat on these regs for 3 years as the problem of youth smoking grew worse, that FDA is now dictating what should be done rather than the states, that our AAA program is pegged to ADAMHA and Congress's policy decision to give states the responsibility, etc.

This, in my mind, is a communications call—do we do press conference, a statement, nothing—I don't have the answers yet. But set forth above are some of the questions. Let me know what you all think. Thanks.

Note for Woodward, Ellis

From: Woodward, Ellis
Date: Wed, Aug 16, 1995 12:49 PM
Subject: RE: Bob Eck
To: Colby, Dolly
Cc: Laufer, David

Dolly: if he is just looking for a copy of the reg, we have here.

From: Colby, Dolly on Wed, Aug 16, 1995 11:25 AM
Name: FW: Bob Eck
Company: Rye Brook
Phone: 8-265-7100
• Telephoned
To: Laufer, David
Cc: McCormick, Brendan; Woodward, Ellis

See below. D.

From: Woodward, Ellis on Tue, Aug 15, 1995 10:02 AM
Name: FW: Bob Eck
To: Colby, Dolly; Laufer, David; Murphy, Virginia
Cc: Goodheart, Jan; McCormick, Brendan

Ginny: this looks like yours. Let me know if it is not. Thanks.

From: McCormick, Brendan on Tue, Aug 15, 1995 9:52 AM
Name: FW: Bob Eck
To: Colby, Dolly; Woodward, Ellis
Cc: Kiley, Debbie; Laufer, David

Can you provide the Trademark Association with a copy of the regs or at least refer him to the right place? Thanks

From: Martin, Maria on Mon, Aug 14, 1995 6:21 PM
Name: Bob Eck